REMARKS

Status of Claims and Amendment

Upon entry of this amendment, which is respectfully requested, claims 17, 21, 24, and 26 will be amended. Claims 1-16, 18-19, and 23 have been canceled.

Claims 17, 24, and 26 have been amended to even further clarify the claimed method for determining whether a subject has been infected with Borna disease virus (BDV). Support for the amendments to claims 17, 24, and 26 may be found at least at Example 1.

Claim 21 has been amended to change the claim dependency.

No new matter is added.

In addition, Applicants thank the Examiner for acknowledgement and entry of the Amendment filed February 26, 2008, in the Advisory Action mailed March 19, 2008.

Applicants thank the Examiner for withdrawing the objections to the claims in view of the Amendment filed February 26, 2008.

Response to Rejections Under § 112, first paragraph

1. Written Description Rejection

On page 3 of the Office Action, the Examiner rejects Claims 17, 20-22 and 24-26 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description.

Specifically, the Examiner states that the claims are drawn to a method of detecting BDV infection in a subject, but that the specification only discloses detection of IgM and IgG antibodies that bind BDV (i.e., not a method of detecting BDV infection).

In addition, the Examiner appears to take the position, in the Advisory Action mailed March 19, 2008, that the measurement of antibody is possible during infection, but not that

detection/measurement of antibody is indicative of "an active" infection.

In response, Applicants note that the rejection is improper for the same reasons presented February 26, 200, because the Examiner has failed to overcome the strong presumption that an adequate written description of the claimed invention is present when the application was filed because a person skilled in the art would readily appreciate that the specification explicitly discloses methods for the detection of an infection by BDV vis-à-vis the presence of IgM and/or IgG specific thereto, which constitutes adequate support for the claims.

Again, Applicants respectfully submit that the specification explicitly discloses methods for the detection of a BDV infection vis-à-vis the presence of IgM and/or IgG specific thereto.

However, solely to advance prosecution of the present application, Applicants have amended the claims to recite that the claimed method is for determining whether a subject has been infected with Borna disease virus (BDV) infection in a subject.

Accordingly, Applicants request withdrawal of the Examiner's rejection.

2. Enablement Rejection

On page 3 of the Office Action, the Examiner rejects Claims 17, 20-22 and 24-26 under 35 U.S.C. § 112, first paragraph as lacking enablement.

Specifically, the Examiner states that while the specification enables a method of detecting antibodies that bind BDV, the Examiner alleges that the specification does not enable a method of detecting a BDV infection.

Further, the Examiner appears to take the position, in the Advisory Action mailed March 19, 2008, that the claims are directed to an "active on-going" infection, and that Carbone

teaches that viruses may or may not be present in subjects that have tested positive for anti-serum because some viruses are cleared while others persist, even with regard to BDV.

In response, Applicants respectfully submit that for the same reasons advanced February 26, 2008, one reasonably skilled in the art would be enabled to make or use the claimed invention from the disclosures in the specification coupled with common information known in the art, without undue experimentation.

However, solely to advance prosecution of the present application, the claims have been amended to recite a claimed method for determining whether a subject has been infected with Borna disease virus (BDV).

With regarding Carbone, Applicants note that as previously presented, the state of the art indicates the opposite of that which the Examiner concludes - that the presence of serum IgM and IgG to BDV are indicative of infection. The Examiner's conclusion that viruses may or may not be present in subjects that have anti-serum is illogical and inconsistent with the cited reference because the Examiner analogizes "infection" with "stages of infection". The claims do not refer to detecting a particular "stage of infection". Thus, the Examiner's comments are irrelevant. Based on Applicants' specification and the state of the art, Applicants respectfully submit that one of skill in the art would appreciate the well-established correlation between Ig production and BDV infection such that only routine laboratory work is required to perform the claimed method of infection detection.

Accordingly, Applicants request withdrawal of the Examiner's rejection.

Response To Rejections Under § 103(a)

On page 5 of the Office Action, the Examiner rejects Claims 17, 20-22 and 24-26 under 35 U.S.C. § 103(a) as being

unpatentable over Yamaguchi et al in view of Watanabe et al, as evidenced by Planz et al further in view of Hatalski et al and Carbone.

In response, Applicants note that for the same reasons advanced February 26, 2008, the present invention is not taught or suggested by Yamaguchi et al, alone or in combination with Watanabe et al, Planz et al, Hatalski et al or Carbone.

Applicants again note that as admitted by the Examiner, Yamaguchi et al fails to disclose p10, as claimed. While Yamaguchi et al may disclose ECLIA methods for detecting p40 and p24, Yamaguchi et al states, "the ECLIA would serve as an excellent screening test to detect BDV antibodies *when combined with more specific tests such as WB analysis* or the binding inhibition assay based on the addition of specific BDV peptides" [emphasis added] (page 354, Discussion). Thus, according to Yamaguchi et al, the method of Yamaguchi et al cannot possibly be used alone to accurately assess BDV infection.

Watanabe et al fails to cure the deficiencies of Yamaguchi et al. because Watanabe et al discloses only WB (Fig. 2). Applicants' ECLIA method cannot be rendered obvious by Watanabe et al because the reference clearly states, "the results in this study [the detection of antibodies to BDV by WB] could be worthy for the establishment of diagnostics methods for BDV infection..." (page 777). The results obtained by Watanabe et al are therefore self-limiting (i.e., to BDV polypeptide detection by WB analysis). This is consistent with the disclosure of Yamaguchi et al, which clearly states that ECLIA must be combined with WB in the detection of BDV.

Thus, the Examiner's argument that ECLIA using p10, p24 and p40 is obvious in light of the cited references is clearly incorrect. The Examiner's legal conclusion is also incorrect. The disclosures of Yamaguchi et al and Watanabe et al fail to

teach each and every element of the claimed invention, and actually teach away from the Applicants' highly sensitive method of detection of BDV infection using ECLIA for p10, p24 and p40.

Furthermore, Planz et al, Hatalski et al and Carbone do not remedy the deficiencies of Watanabe et al and Yamaguchi et al.

Thus, Applicants request withdrawal of the Examiner's rejection under 35 U.S.C. § 103(a).

Conclusion

In view of the amendments to the claims and the arguments set forth above, reconsideration and allowance of this application are respectfully requested.

The Examiner is invited to contact the undersigned at the below listed number on any questions which might arise.

Respectfully submitted,

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